Attorney Docket No. SANS2.002

8/8/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: ANDRE et al.

Serial No.: 10/019,588

Filed: December 20,2001

Group Art Unit: 1615

Examiner: Blessing M. Fubara

For: PHARMACEUTICAL DOSAGE FORMS FOR CONTROLLED RELEASE PRODUCING AT LEAST A TIMED PULSE

CERTIFICATE UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being deposited on the date indicated below with the United States Postal Service as first class mail addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Geraldine Asher
Name

July 23, 2003
Date

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

RESPONSE

This is responsive to the Office Action mailed March 26, 2003 (Paper No. 5), setting a one-month period for response expiring April 25, 2003. Pursuant to the Petition for Extension of Time under 37 C.F.R. 1.136(a) submitted herewith, the period for response is extended three months to expire July 25, 2003. This response is therefore timely filed.

Claims 1-4, 6-9, and 11-34 are in the application.

Restriction is required on the grounds that the claims are directed to more than one species of the generic invention, which species purportedly are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are defined by the Examiner as compositions containing all permutations of the following elements:

a matrix that is free of active agent,
a matrix that contains active agent,
cationic surfactants,
zwitterionic surfactants,
alfuzosin as active substance, and
a hypnotic as active substance.

The claims are stated to correspond to the above species as follows:

I. Claims 1-4, 7-9, 11-22, and 24-33 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is

embedded in a rapidly disintegrating matrix that has an active substance and where the active substance in the delayed release coated core is alfuzosin.

II. Claims 1-4, 7-9, 11-22, 24-32, and 34 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that has an active substance and where the active substances in the delayed release coated core is a hypnotic.

III. Claims 1-4, 6-9, 11-22, and 24-33 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that has as active substance and where the active substance in the delayed release coated core is alfuzosin.

IV. Claims 1-4, 6-9, 11-22, 24-32, and 34 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that has as active substance and where the active substance in the delayed release coated core is a hypnotic.

V. Claims 1-4, 7-9, 11-23, and 25-33 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of active substance and where the active substance in the delayed release coated core is alfuzosin.

VI. Claims 1-4, 7-9, 11-23, 25-32, and 34 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of active substance and where the active substance in the delayed release coated core is a hypnotic.

VII. Claims 1-4, 6-9, 11-23, and 25-33 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of an active substance and where the active substance in the delayed release coated core is alfuzosin.

VIII. Claims 1-4, 6-9, 11-23, 25-32, and 34 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of an active substance and where the active substance in the delayed release coated core is a hypnotic.

The restriction requirement is respectfully traversed and reconsideration thereof is requested. The invention relates to controlled release dosage forms that produce a timed pulse release of a pharmaceutical substance. The different species referred to by the

Examiner are simply different embodiments of the single invention concept of that timed release dosage form and, hence, the claims thereto should be examined together. Moreover, the species identified by the Examiner are limited to those compositions in which the coated core is embedded in a rapidly disintegrating matrix, i.e., the subject of claims 20-28 and 31-34. It is not clear whether the Examiner considers the coated core of claims 1-19, 29, and 30 as also comprising multiple patentability distinct species. Reconsideration of the restriction requirement is requested.

Nevertheless, in order that this response be complete, Applicants hereby elect with traverse the species wherein the matrix is free of active substance, the surfactant is zwitterionic and the active substance is alfuzosin, which species is read on by claims 1-4, 6-9, 11-23, and 25-33, Examiner's Group VII.

This application is believed in condition for reconsideration and action on the merits, and such actions are earnestly solicited.

Respectfully submitted,

Date: 11/23/03

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